Novo Nordisk Inc. Response to 12-month Follow-up for Evidence Regarding "Medications for Obesity Management: Effectiveness and Value" Report

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Novo Nordisk Inc. appreciates the opportunity to submit new evidence regarding semaglutide 2.4 mg since the publication of the report entitled, "Medications for Obesity Management: Effectiveness and Value" published on October 20th, 2022.

As part of its review, Novo Nordisk respectfully encourages ICER to consider the following new evidence and coverage updates to be included as an addendum to the existing report:

Since the release of ICER's Final Evidence Report on October 20th, 2022, several publications and congress presentations have continued to add evidence of clinical benefits of semaglutide 2.4 mg, as an effective treatment option for chronic weight management among those living with obesity or overweight in the presence of one or more weight-related complications. The SELECT cardiovascular outcomes trial demonstrated superiority of semaglutide 2.4 mg versus placebo, showing a reduction in the risk of MACE when added to standard of care in people with established cardiovascular disease (CVD) with overweight or obesity and no prior history of diabetes. Novo Nordisk Inc. has filed for a label update for semaglutide 2.4 mg to include a new indication for reducing the risk of major adverse cardiovascular events (MACE), which includes death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke, in people with an initial BMI of 27 kg/m^2 or greater and established CVD. Notably, the Food and Drug Administration (FDA) recently granted Priority Review for the supplement including the SELECT data and a decision for updating the semaglutide 2.4 mg indication is expected in 2024[1]. Applicable literature from the post-assessment period is included in Appendix A.

Heart failure with preserved ejection fraction (HFpEF) represents a considerable unmet medical need with increasing incidence, and substantial morbidity and mortality. In the STEP HFpEF trial, semaglutide 2.4 mg improved heart failure-related symptoms, physical limitations, exercise function, and reduced body weight and inflammation in patients with obesity and HFpEF.[2] Secondary analyses from the STEP HFpEF trial by baseline obesity class, left ventricular ejection fraction, Kansas City Cardiomyopathy Questionnaire (KCCQ) scores, and body weight reduction category further support semaglutide-mediated weight reduction as a key therapeutic strategy in patients with obesity-related HFpEF.[3,4,5]

The prevalence of obesity among adolescents is rising and predicted to double by 2030. Adolescents with obesity are at a higher risk of developing serious health problems at a younger

[1] News details (novonordisk-us.com)
[2] Kosiborod MN., Abildstrøm SZ., Borlaug BA. et al. Semaglutide in Patients with Heart Failure with Preserved Ejection Fraction and Obesity. N Engl J Med 2023; 389:1069-1084. DOI: 10.1056/NEJMoa2306963
[3] Borlaug BA, Kitzman DW, Davies MJ, et al. Semaglutide in HFpEF across obesity class and by body weight reduction: a prespecified analysis of the STEP-HFpEF trial. Nat Med. 2023 Sep;29(9):2358-2365. doi: 10.1038/s41591-023-02526-x. Epub 2023 Aug 27
[4] Butler J, Abildstrøm SZ, Borlaug BA, et al. Semaglutide in Patients With Obesity and Heart Failure Across Mildly Reduced or Preserved Ejection Fraction J Am Coll Cardiol 2023;82:2087–2096
[5] Kosiborod MN, Verma S, Borlaug BA, et al. Effects of Semaglutide on Symptoms, Function, and Quality of Life in Patients with Heart Failure with Preserved Ejection Fraction and Obesity: A Prespecified Analysis of the STEP-HFpEF Trial. Circulation. 2023 Nov 12. doi: 10.1161/CIRCULATIONAHA.123.067505. Online ahead of print

age. In the STEP TEENS trial of adolescent (12 to <18 years of age) patients with obesity (BMI in the 95th percentile or higher), once-weekly treatment with semaglutide 2.4 mg plus lifestyle intervention resulted in a greater reduction in BMI than lifestyle intervention alone, further highlighting the clinical benefits of semaglutide 2.4 mg for obesity management in this segment of the population.[6]

[6] Weghuber D., Barrett T., Barrientos-Perez M. et al. Once-Weekly Semaglutide in Adolescents with Obesity. N Engl J Med 2022; 387:2245-2257. DOI: 10.1056/NEJMoa2208601

Appendix A – Literature for review

1. Lincoff AM., Brown-Frandsen K., Colhoun HM. et al. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. N Engl J Med 2023; 389:2221-2232. DOI: 10.1056/NEJMoa2307563

2. Kosiborod MN., Abildstrøm SZ., Borlaug BA. et al. Semaglutide in Patients with Heart Failure with Preserved Ejection Fraction and Obesity. N Engl J Med 2023; 389:1069-1084. DOI: 10.1056/NEJMoa2306963

3. Borlaug BA, Kitzman DW, Davies MJ, et al. Semaglutide in HFpEF across obesity class and by body weight reduction: a prespecified analysis of the STEP-HFpEF trial. *Nat Med*. 2023 Sep;29(9):2358-2365. doi: 10.1038/s41591-023-02526-x. Epub 2023 Aug 27

4. Butler J, Abildstrøm SZ, Borlaug BA, et al. Semaglutide in Patients With Obesity and Heart Failure Across Mildly Reduced or Preserved Ejection Fraction *J Am Coll Cardiol* 2023;82:2087–2096

5. Kosiborod MN, Verma S, Borlaug BA, et al. Effects of Semaglutide on Symptoms, Function, and Quality of Life in Patients with Heart Failure with Preserved Ejection Fraction and Obesity: A Prespecified Analysis of the STEP-HFpEF Trial. *Circulation*. 2023 Nov 12. doi: 10.1161/CIRCULATIONAHA.123.067505. Online ahead of print

6. Weghuber D., Barrett T., Barrientos-Perez M. et al. Once-Weekly Semaglutide in Adolescents with Obesity. N Engl J Med 2022; 387:2245-2257. DOI: 10.1056/NEJMoa2208601

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Institute for Clinical and Economic Review
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Dear ICER Colleagues:

On behalf of the Obesity Action Coalition (OAC) and our 80,000 members across the United States, I'd like to thank you for the opportunity to provide additional comments on ICER's review on Anti-Obesity Medications.

I would like to start by thanking ICER for recognizing and including the experiences of people living with obesity in thereport and for your broad accounting of the value of obesity treatment.

A number of significant changes have taken place in the past year that are worth consideration:

- Tirzepatide was recently approved by FDA for obesity care and brings another new agent to the arsenal of obesity treatments.
- Widespread medication shortages including semaglutide, liraglutide and other GLP-1's used off-label have created significant disruption in obesity care. Add these shortages to the already challenging insurance coverage pointed out in your report and patients are truly struggling finding consistent, life changing and lifesaving care. Manufacturer reports indicate that such shortages may be the norm for the foreseeable future likely significantly limiting the number of patients who can seek obesity care even if they have coverage. These limitations of supply have not been included in any considerations of obesity care utilization and cost that we've seen to date.
- More information about rebates is now available estimating rebates are between 48% and 79% for the newest GLP-1 medications. This is significantly higher than the rebates in the report. In addition, newly approved tirzepatide has a list price approximately 21% less than semaglutide for obesity which we believe is the start of significant price reductions in the future for GLP-1's and their related combinations.
- Significant health benefit data of semaglutide including the SELECT trial showing a 20% reduction in cardiovascular events, STEP-HFpEF on heart failure and the soon to be published FLOW trial on CKD all likely also increase the value of treatment.
- Insurance coverage appears to be improving slowly with the narrative shifting from not covering AOM's at all due to cost to trying to find the right level of coverage and benefit design. Progress has been intermittent with some backtracking (reducing or ending coverage) in some plans.

A number of factors have not changed over the past year:

- Hype. Media interest around new obesity treatments continues at all time high and reflects often exaggerated costs (not including rebates) and utilization (not reflecting significant drug shortages)
- High quality/comprehensive patient assistance programs, going beyond patient co-pay cards, are still lacking.

- Limited or no coverage for obesity medications often has patients paying list prices for medicines, if they can be found, or turning to compounded products with unknown origins or safety.

Thank you again for ICER's continued work on this important topic and for considering more than just short-term costs in your analysis. The intent of healthcare is to improve people's health outcomes and quality of life, not just save money.

Sincerely,

Joseph Nadglowski, Jr.
President/CEO